REMARKS

Claims 54, 55 and 68 have been canceled.

Claim 64 has been amended. Specifically, the claim now specifies that the cancer cells therein are metastatic cells, and that the expression of Fas ligand induces apoptosis in the metastatic cancer cells. Support for these amendments can be found in the specification, for example, on page 55, lines 11-28. Accordingly, Applicants submit that no new matter has been entered into the application.

Claim 66 has been amended to remove "leukemia" from the list of recited cancers.

I. Interview Summary

On March 19, 2009, Applicants and their representatives conducted a telephonic interview with the Examiner. The claim amendments entered herein were discussed, and the Examiner indicated such amendments would render the claims novel over the cited prior art. Applicants indicated they would be willing to submit a Declaration regarding the ability of locally injected FasL expressing vectors to treat distant tumors. The Examiner noted that he was not able to address any potential 35 U.S.C. §103 issues as further searching would be required in view of the suggested amendments.

II. Rejections Under 35 U.S.C. §102 – anticipation

The Examiner has rejected Claims 64, 66 and 69 as being anticipated by Arai et al. (PNAS 94(25):13862-13867, 1997). The Examiner cites Arai et al. as teaching that gene transfer of Fas ligand induces tumor regression *in vivo* and that tumor regression follows injection of the tumor with adenoviral vectors expressing Fas ligand (ADV-FasL). Additionally, the Examiner cites Arai et al. as teaching that "...gene transfer of FasL may compensate for locally suppressive immune effects on tumor recognition..." The Examiner thus concludes that the teaching of Arai et al. anticipates the pending claims.

Applicants note that Claim 64 has been amended to recite the induction of apoptosis in metastatic cancer cells. As was discussed in the interview of March 19, 2009, Arai et al. disclose that injection of FasL ligand-encoding DNA into a tumor results in regression of that local tumor.

In contrast, the instant invention is now drawn to a method of inducing apoptosis in metastatic cancer cells. Arai et al. does not contain any disclosure regarding metastatic cancer cells. Thus, as noted by the Examiner in the interview, "the prior art does not anticipate the invention."

In view of the above, Applicants request that the rejection of Claims 64, 66 and 69 as anticipated by Arai et al. be withdrawn.

III. Rejections Under 35 U.S.C. §112, first-paragraph –enablement

The Examiner has rejected Claims 54-55, 64, 66, 68 and 69 for lack of enablement. Specifically, the Examiner states that while the specification is enabling for a method of inducing apoptosis in cancer cells in a solid tumor, it does not enable the treatment of cancer cells that are not in solid tumors (i.e., leukemia).

Applicants note that Claims 54, 55 and 68 have been canceled, and Claim 66 has been amended, rendering this rejection moot.

With regard to the ability of the instant invention to treat metastatic cancer, Applicants submit herewith Declarations by co-inventors Dr. Donald Bellgrau, and Dr. Richard Duke detailing a scientific study that demonstrates the effect of locally injected adenovirus expressing Fas ligand (Ad-FasL) on survival outcome in dogs having osteosarcoma cells that have metastasized. Applicants respectfully assert that these Declarations establish that the method of the instant invention is effective for treating metastatic cancer.

CONCLUSION

In light of the foregoing amendments and remarks, Applicants believe that the pending claims are in condition for allowance. The Examiner is invited to contact the undersigned at (303) 764-3014 should any issues remain.

Respectfully submitted,
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